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(71) Applicant: **Fuji Systems Kabushiki Kaisha**
Tokyo (JP)

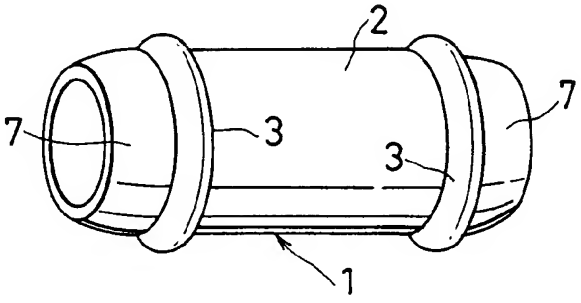
(72) Inventor: **Igarashi, Akira**
Yokohama-shi, Kanagawa (JP)

(74) Representative: **Hildyard, Edward Martin**
Frank B. Dehn & Co.
Imperial House
15-19 Kingsway
London WC2B 6UZ (GB)

(54) Stent for intracorporeal retention

(57) This stent for intracorporeal retention is retained in a human body, for instance, inside an air way, oesophagus, or bile duct, and used for preventing a bore of the internal organs as described above from being occluded. With this stent, discharge from the air way can not easily be adhered to, nor deposited on the internal surface of the cylindrical body, so that occlusion thereof can effectively be prevented, and at the same time granulation is not easily formed, and for this reason occlusion of the air way can be prevented, which insures a high degree of safety for a human body. This stent has a hollow cylindrical body 2 made from silicone rubber with both edges opened, an internal surface of this cylindrical body is processed in any of the following ways: (a) coating with silicone resin, (b) adhesion of a fluorine-based resin tube, or (c) chemical deposition of polyparaxylylene or a derivatives thereof, and at the same time an external surface thereof is processed by (d) chemical deposition of polyparaxylylene or a derivatives thereof or (e) by gradually rounded and tapered toward both edges with the tapered sections softer than other portions thereof.

FIG. 2



EP 0 716 834 A1

Description

The present invention relates to a stent retained in a human body, for instance, inside an air way, oesophagus, or bile duct, and for preventing a bore of the internal organs as described above from being obturated.

Conventionally, a stent made from silicone rubber is used against stenosis of an air way such as a trachea or a bronchus, and the stent is retained at a position of stenosis to enlarge the section thereby for keeping open the air way which is otherwise closed, causing difficulty in respiration. A stent which has been known as the stent 01 described above is shown in Fig.1 and has a cylindrical body 02 with both edges opened, and a plurality of small cylindrical-shaped projections 03 are arranged on the peripheral surface of this cylindrical body 02 to prevent movement of the stent after retained. A method of inserting this stent 01 is generally performed by using a rigid broncho-scope not shown herein, after a body has been subjected to general anesthesia. Namely a rigid broncho-scope comprises, for instance, an external cylinder for a rigid broncho-scope and introducer, and bronchoscopy is generally performed by squashing the stent in its radial direction, inserting the squashed stent into an introducer, then inserting the introducer into the external cylinder of a rigid broncho-scope, and pushing out the stent 01 therefrom with a pusher.

The conventional type of stent 01 described above has such advantages that the stent can safely be retained in a bore of the internal organs, and can be taken out or exchanged with a new one after initial insertion, but on the other hand, the stent has also the danger that discharges from the air way easily adhere to and is deposited on the internal surface of the cylindrical body 02, and the cylindrical body is sometimes occluded thereby. It has also the danger that sometimes granulation is formed at a position where the cylindrical body 02 and the site of stenosis contact each other, because the both edges of the cylindrical body 02 give stimulation to tissue of the trachea or bronchus at positions contacted by the edges all the time with respiratory movement, and once granulation is generated and develops, the air way may be occluded by the granulation.

The present invention was made in the light of the circumstances as described above, and it is an object of the present invention to provide a stent which is extremely safe for a human body because discharge from an air way hardly adheres to and is hardly deposited on the internal surface of a cylindrical body and thus the cylindrical body can be prevented from being occluded thereby, and also because granulation is not easily formed at the both edges of the cylindrical body and thus the air way can be prevented from being occluded thereby.

The stent according to the present invention has a hollow cylindrical body made from silicone rubber with both edges opened for achieving the object described above, and an internal surface of this cylindrical body is processed in any of the following ways: (a) coating with silicone resin, (b) adhesion of a fluorine-based resin tube, or (c) chemical deposition of polyparaxylylene or a derivatives thereof, and at the same time an external surface thereof is processed in either of the following ways: (d) chemical deposition of polyparaxylylene or a derivatives thereof and (e) gradually rounded and tapered toward both edges with the tapered sections softer than other portions thereof. If the internal surface of the cylindrical body is formed as described above, the internal surface thereof is flexible, resistant to adhesion of discharge from the air way, and excellent in lubricity. Also if the external surface of the cylindrical body is formed as described above, the external surface thereof gives less stimulation to the tissue in trachea, and for this reason granulation is not easily formed. Silicone resin coating the internal surface of the cylindrical body comprises block polymer having a resin segment and oil segment in an identical molecule, and this block polymer solution is prepared, for instance, as follows. Silane having a hydrolytic group indicated by $RSiX_3$ is added to an organic solution of block polymer obtained by mixing liquid-phase dimethylpolysiloxane (A) having end reactivity and reactive oligomer (B) including SiOH group obtained by hydrolizing $C_6H_5SiCl_3$ in organic solution at a mixing ratio of A/B = 10/90 to 90/10 (by weight), preferably at a mixing ratio of A/B = 60/40 to 80/20 (by weight) and thermally condensing the mixture in an organic solvent so that ratio of the silane therein becomes X/OH>> 1, and with the operation described above the target crosslinkable block polymer solution can be obtained.

Herein R is selected from a monohydrocarbon group, and

X is selected from a group including:

$$OCH_3,\ OCOCH_3,\ ON{=}C\begin{matrix}CH_3\\C_2H_5\end{matrix}$$

Furthermore, to increase lubricity for preventing adhesion of discharge from the air way, the internal surface of the cylindrical body is coated with a solution obtained by adding high-viscosity silicone oil with the viscosity preferably within a range from 10,000 to one million CS by 0.01 g to 3.5 g, and preferably 0.5 g to 1.5 g to 100 ml of a solution of silicone resin (percentage of nonvolatile ingredients: 23 %) which is a solution of the crosslinkable block polymer described above and sufficiently dissolving therein, and then thermally hardening the coating. Dimethyl silicone oil is suited for the silicone oil to be used herein, but it is not limited thereto. Also silicone oil having higher-viscosity than one million CS can be used for this purpose without causing any problem. If this silicone oil is excessively added thereto, strength of the coating layer becomes extremely low, and also adhesiveness of the coating lowers, which is not preferable because the coating is easily peeled off,

or hardening fault occurs in the coating layer. Raw rubber which is a high polymer methylpolysiloxane of silicone may be used in place of the silicone oil described above, but dissolving the raw rubber to silicone resin solution (percentage of nonvolatile ingredients : 23 %) takes a long time, which is not preferable in practical use, so that it is convenient to use silicone raw rubber dissolved in silicone oil. In this case, increase in adhesiveness can similarly be achieved by coating with a solution obtained by adding, for instance, raw rubber dissolved in silicone oil with the raw rubber content of 20 % to 100ml of silicone resin solution (percentage of nonvolatile ingredients: 23%) by 0.01 g to 10 g, preferably 1 g to 7 g, and for this reason adhesion of discharge from the air way to the internal surface thereof can be prevented. Also solution such as organic solution in which raw rubber is previously dissolved may be used in place of the raw rubber dissolved in silicone oil as described above.

It is desirable that a fluorine-based resin tube adhered to the internal surface of the cylindrical body has a thickness of 0.01 mm to 0.3 mm. Resin used for this purpose is not always limited to a fluororesin, and any type of resin may be used so long as it is a fluorine-based resin. By chemically depositing paraxylylene or a derivatives thereof on the peripheral surface of the cylindrical body, the capability to suppress formation of granulation not obtained with silicone rubber can be obtained. Also the external surface of the cylindrical body gradually rounded and tapered toward the both edges with the tapered sections softer than other portions insures the tendency to suppress formation of granulation, which can not be achieved with silicone rubber that is of homogeneous hardness in the entire body. A soft portion can be in any place of the external surface of cylindrical body as long as a place is in contact with the tissue of trachea, but it is especially desired to provide the soft sections in both edges.

As described above, with the present invention, it becomes possible to obtain a stent in which discharge from the air way can not easily be adhered to the internal surface of the cylindrical body, the external surface thereof less stimulates the trachea tissue, and granulation is not easily formed therein. Also discharge from the air way can not easily be adhered to, nor deposited on the internal surface of the cylindrical body, so that occlusion thereof can effectively be prevented, and at the same time granulation is not easily formed, and for this reason occlusion of the air way can be prevented, which insures a high degree of safety for a human body.

In a stent prepared according to one of the preferred modes for carrying out the present invention, silicone resin layer is formed so that it covers an internal surface of the cylindrical body, an external surface of each edge section is notched, a silicone rubber layer softer than the cylindrical body is formed in each of the notched sections, and an external surface of the silicone rubber layer is gradually rounded and tapered toward the edge. Also in a stent prepared according to another mode for carrying out the present invention, a fluorine-based resin layer is formed so that it covers an internal surface of the cylindrical body, an external surface of each edge section is notched, a silicone rubber layer softer than the cylindrical body is formed in the notched section, and an external surface of the silicone rubber layer is gradually rounded and tapered toward the edge. Also in a stent prepared according to a further different mode for carrying out the present invention, an external surface of each edge section of the cylindrical body is notched, a silicone rubber layer softer than the cylindrical body is formed in the notched section, an external surface of the silicone rubber layer is gradually rounded and tapered toward the edge, and a layer made from polyparaxylylene or a derivatives thereof is formed so that it covers an internal and an external surface of the cylindrical body including the silicone rubber layer. Also in a stent prepared according to still another mode for carrying out the present invention, a fluorine-based resin layer is formed so that it covers an internal surface of the cylindrical body, an external surface of each section is notched, a silicone rubber layer softer than the cylindrical body is formed in the notched section, an external surface of the silicone rubber layer is gradually rounded and tapered toward the edge, and a layer made from polyparaxylylene or a derivatives thereof is formed so that it covers an external surface of the cylindrical body including the silicone rubber layer. And in a stent prepared according to other mode for carrying out the present invention, a peripheral rib for positioning and preventing movement of the stent after retained are provided in both side sections on an external surface of the cylindrical body. As a peripheral rib of this stent, it is desirable to provide a circular rib or an articulated rib with a portion notched in the peripheral direction thereof so that the cylindrical body can be squashed in the radial direction thereof. The peripheral rib may be monolithically formed with the cylindrical body. In a case of the stent in this mode, the stent is inserted into a rigid broncho-scope in its squashed state and the broncho-scope is inserted into an human body such as trachea and can be retained therein, which insures further convenience. In addition, it is possible to insert the stent, when squashed, into a rigid broncho-scope having a thinner bore, so that a scope where the stent is applicable is widened, which is extremely useful for patients as well.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig.1 is a perspective view showing a conventional type of stent;

Fig.2 is a perspective view showing a stent as a whole according to one of the most preferred embodiments of the present invention;

Fig.3 is a partially enlarged vertical sectional view showing a stent;

Fig.4 is a partially enlarged vertical sectional view

showing a stent according to Embodiment 2 of the present invention;

Fig.5 is a partially enlarged vertical sectional view showing a stent according to Embodiment 3 of the present invention;

Fig.6 is a partially enlarged vertical sectional view showing a stent according to Embodiment 4 of present invention;

Fig.7A to Fig.7E are partially sectional views each showing a modification of a notched section and a silicone rubber layer of the cylindrical body;

Fig.8 is an explanatory view showing effects thereof;

Fig.9 is a perspective view showing a stent as a whole according to Embodiment 5 of the present invention; and

Fig.10 is an enlarged side view of Fig.9.

In Fig.2 and Fig.3, the reference number 1 indicates a stent, which has a hollow cylindrical body 2 made from silicone rubber with both edges opened, and circular ribs 3 each as a peripheral rib are monolithically provided in the both edges of the external surface thereof. The rib 3 has a function of preventing movement of the stent 1 after retained like a projection 03 in the conventional type thereof. A silicone resin layer 4 is formed by coating with silicone resin an internal surface of the cylindrical body 2 so that it covers the internal surface thereof. Also the external surface of each edge of the cylindrical body 2 which is located at a position outer from the rib 3 is notched with inward inclination, a silicone rubber layer 6 softer than the cylindrical body 2 is adhered to the notched section 5 with an adhesive. The external surface 7 of silicone rubber layer 6 is gradually rounded and tapered toward the edge.

Description is made for an example of preparation of the stent 1. 15 parts of the barium sulfate and 1.3 parts of the vulcanizing agent are added to 100 parts of the silicone rubber KE1551U with a hardness of 55 (JIS K6301 A type) (Japanese Industrial Standard) produced by SHIN'ETSU CHEMICAL INDUSTRY CO. and an unvulcanized silicone rubber sheet well-mixed by a roll is molded in a mold for a stent, and is pressed by a press under a temperature of 130 °C for 15 minutes, and then the mold is opened to pull out a core metal from the stent 1 made from silicone rubber which is a molded product, and a stent 1 made from silicone rubber with its external surface 7 of each edge gradually rounded and tapered toward the edge as shown in Fig.2 can be obtained. This stent 1 is subjected to an after vulcanization in an oven under a temperature of 180 °C for 8 hours to remove reactive residues therefrom. Then the external surface of each edges of this stent 1 is trimmed and notched with inward inclination toward the bore of the stent by a grinding machine such as a grinder, and a silicone rubber layer 6 with a hardness of 1 (JIS K6301 A type) is adhered to this notched section 5. After this step, the internal surface of the stent 1 is coated with a solution of silicone resin in the order of 1), 2), and 3) as described below.

1) Silicone resin solution with a content of nonvolatile ingredients of 23% comprising a block polymer having a resin segment and an oil segment in one molecule.

2) Solution obtained by adding 1.5 g of silicone oil KF96H - 100,000 with viscosity of 100,000 CS to 100 ml of the silicone resin solution 1) described above and sufficiently agitating and dissolving therein.

3) Solution obtained by adding 5 g of a raw rubber dissolved in a silicone oil with a raw rubber content of 20 % to 100 ml of the silicone resin solution of 1) described above and sufficiently agitating and dissolving it therein.

After coating with these solutions, the coating is sufficiently air-dried and solvent therein volatiled, and then heated for hardening in an oven under a temperature of 160 °C for one hour, when a silicone resin layer 4 is formed in which discharge from the air way is not easily adhered to the internal surface thereof.

Because the silicone rubber layer 6 with a hardness of 1 (JIS K6301 A type) is formed on the external surface of each edge of the stent 1 as described above, the external surface thereof becomes softer than the cylindrical body 2, which insures excellent capability to suppress formation of granulation. Namely a silicone rubber layer 6 softer than the cylindrical body 2 is provided on the external surface of each edge thereof, and force generated when the each edge of the cylindrical body 2 is mechanically contacting the internal surface of a trachea is made weaker thereby, and for this reason, it becomes possible to delay and suppress formation of granulation. In a case where the external surface of each edge of the cylindrical body 2 is notched for tapering, force generated when contacting the internal surface of a trachea can be made weaker, but if there are sharp edges on the surface, the edges stimulate the internal surface of the air way, which is not preferable. Also, if the edge section is thin, it is weak in strength which causes the edge section to be easily dented toward the side of bore of the cylindrical body, which is also undesirable. Namely it is desirable that the edge section is appropriately round and soft enough to enable weakening of the force generated when contacting the internal surface of trachea, and has an appropriate strength for the edge section not to be easily dented toward the bore of the stent. Generally as a hardness (JIS K6301 A type) required for a trachea stent, a silicone rubber with a hardness of approximately 60 is used, so that softer silicone rubber provided on the external surface of each edge should have a hardness of less than 30 in JIS K6301 A type, and preferably of less than 10, and in a case where silicone gel softer than a silicone rubber is used, it is desirable that a degree of insertion with a pin

(hardness) is less than 150, and preferably less than 100 under the conditions of JIS K2220, 1/4 cone, and the whole load of 9.38 g. But, if the hardness thereof becomes too low, the mechanical strength sometimes becomes lowers, with the adhesive force weakened, and a tack touch appears on the surface thereof, which is not preferable.

Fig.4 is a partially enlarged vertical sectional view showing a stent according to Embodiment 2 of the present invention. This stent 11 is different from that according to Embodiment 1 in that a fluorine-based resin layer 14 is formed in the internal surface 2 of the cylindrical body 2 in place of the silicone rubber layer 4 described above, but the rest portion is the same as those in Embodiment 1. The fluorine-based resin layer 14 is formed by, for instance, adhering a tube made from a fluorine-based resin to the internal surface of the cylindrical body 2.

Description is made for an example of preparation of a stent 11. 4.0 parts of the vulcanizing agent C-4 is added to 100 parts of the silicone rubber KE540U having a hardness of 40 produced by SHIN'ETSU CHEMICAL INDUSTRY CO. and an unvulcanized rubber sheet mixed sufficiently by a roll is prepared. Then a silane-based primer for a silicone rubber is applied to the external surface of a tube made from fluororesin PFA (A copolymer of tetrafluoro-ethylene ~perfluoroalkylvinylether) having an outer diameter of 8.0 mmϕ, a wall thickness of 0.05 mm, and a length of 30 mm, said external surface having been subjected to processing with ammonia solution of metallic sodium, and air-dried. Then a core metal with an outer diameter of approximately 7.90 mmϕ is inserted into a bore of this tube made from PFA without clearance between them. And the unvulcanized silicone rubber sheet described above previously prepared is placed in space of the stent mold by using the core metal covered by this PFA tube, is pressed by a press under a temperature of 170 °C for 20 minutes to thermally harden the silicone rubber, and at the same time the silicone rubber is hardened and adhered to the external surface of the PFA tube. Then, after pressed, the mold is opened, and the core metal is pull out from the tube-shaped stent 11 made from silicone rubber adhered with the PFA tube to the internal surface thereof, and the stent 11 made from silicone rubber comprising a thin tube made from PFA with the internal surface covered with fluororesin is obtained. This stent is subjected to a after vulcanization in an oven under a temperature of 180 °C for 8 hours to remove reactive residues. Then the external surface of each edge of this stent 11 is notched like in Embodiment 1, and the silicone rubber layer 6 is adhered thereto.

A thickness of the tube made from fluororesin in the internal surface is in a range from 0.01 mm to 0.3 mm as described above, and preferably in a range from 0.03 mm to 0.1 mm, and if it is less than the value described above, it is difficult to produce a tube and the physical strength becomes weak, and if the thickness is more than the value described above, flexibility of the stent 11 is reduced and the stent does not conform to a biological tissue such as trachea. The tube made from silicone rubber is inserted so that it contacts the internal surface of this stent 11 to mask the internal surface of the stent, and then a thin film of poly-monochrolo-para-xylylene is provided on the external surface thereof. After the thin film has been provided thereon, the tube described above is removed.

Fig.5 is a partially enlarged vertical sectional view showing a stent according to Embodiment 3 of the present invention. This stent 21 is different from Embodiment 2 in that a layer 17 of poly-monochrolo-para-xylylene which is one of derivatives of polyparaxylylene is formed in the internal and external surface of the cylindrical body 2 in place of the fluorine-based resin layer 14 described above so that it covers the internal and external surface thereof, and portions other than that are the same as those in Embodiment 2. The layer 17 of poly-monochrolo-para-xylylene is formed by chemically depositing poly-monochrolo-para-xylylene in the internal and external surface of the cylindrical body 2.

Description is made for an example of preparation of a stent 21. Poly-monochrolo-para-xylylene which is one of derivatives of polyparaxylylene is chemically deposited on the internal and external surface of the cylindrical body 2 by using a molded stent like in Embodiment 1 in the following processing sequence: ① vaporization of dimer from poly-monochrolo-para-xylylene having been subjected to chemical deposition in a vaporization room → ② generation of diradical-monochrolo-para-xylylene by thermally decomposing the dimer in a thermal decomposition room → ③ adsorption of diradical-monochrolo-para-xylylene and formation of strong deposition of a thin film made from polymerized and high molecular weight poly-monochrolo-para-xylylene to the internal and external surface of the cylindrical body 2 → ④ an exhausting process. A stent 21 made from silicone rubber is obtained according to the sequence described above. As a thickness of a thin film deposited by polyparaxylylene or a derivatives thereof, a range from 0.01 μm to 20 μm is required and preferably a range from 0.1 μm to 5 μm is preferable. If it is too thin, its lubricity becomes lower, and on the other hand, if it is too thick, a deposited film has less flexibility, and for this reason, when it is bent, cracking occurs therein, which is disadvantageous in practical use. Discharge from an air way is prevented from adherence and deposition to the internal surface of a stent 21 and forming granulation between the external surface of each edge of the stent 21 and the internal surface of trachea can be delayed or suppressed by lubricity of the surface excellent in chemical resistance not obtained with silicone rubber and by adaptability to a living body preventing deposition of this polyparaxylene or a derivatives thereof to the internal and external surface of the stent 21 made from silicone rubber.

Fig.6 is a partially enlarged vertical sectional view

showing a stent according to embodiment 4 of the present invention. This stent 31 is different from Embodiment 2 in that polyparaxylylene or a derivatives layer 37 thereof is formed on the external surface of the cylindrical body 2 according to Embodiment 2, and positions other than that are the same as those in Embodiment 2.

A shape of the notched section 5 and a shape of silicone rubber layer 6 formed therein in each embodiment described above indicate only an example, and it is needless to say that any shape other than those shown in figures may be employed. Fig.7A to Fig.7E each are modifications thereof, and in Fig.7A, the notched section 5a is formed by two faces; one face perpendicular to the axis extending from the external surface to the side of internal surface thereof and another face extending from the edge of internal surface to downward inclination, and a silicone rubber layer 6a conforming thereto is adhered and formed in the section. In Fig.7B, the notched section 5b is formed by two faces; a face perpendicular to the axis extending from the external surface to the side of internal surface and another face extending in parallel to the axis from the edge of internal surface, and a silicone rubber layer 6b conforming thereto is adhered and formed in the section. In Fig.7C, the notched section 5c is formed by three faces; a face perpendicular to the axis extending from the external surface to the side of internal surface, a face extending in parallel to the axis from the edge of internal surface, and a face perpendicular to the axis extending from the edge of the end to the side of internal surface, and a silicone rubber layer 6c conforming thereto is adhered and formed in the section. In Fig.7D, the notched section 5d is formed by faces perpendicular to the axis extending from the external surface to the side of internal surface, and a silicone rubber layer 6d conforming thereto is adhered and formed in the section. In Fig.7E, the notched section 5e is formed by a curved face extending from the external surface to the internal surface, and a silicone rubber layer 6e conforming thereto is adhered and formed in the section.

Fig.8 shows stents 1, 11, 21, and 31 according to each embodiment described above in a retained state in a section of stenosis of a trachea by pushing out each of the stents by a rigid broncho-scope under general anesthesia and by inserting it thereto. As clearly understood from Fig.8, each rib 3 has a function so that it is engaged in the internal surface of a bore of a section of stenosis and prevents movement of each of the stents 1, 11, 21, and 31, and with this function to prevent movement the stent enlarges a section of stenosis and prevents it from being occluded.

It should be noted that each embodiment shown in figures is provided only as a preferable example, and each embodiment described above is not intended to limit this invention. Namely, it is also possible to obtain the same effect as that obtained in each embodiment, for instance, by covering the internal surface of the cylindrical body 2 with a silicone resin layer 4 and by covering the external surface with a polyparaxylylene layer 37, and also such configuration is allowable that an external surface of each edge on the cylindrical body 2 is notched, and soft silicone rubber layer 6 is formed in the notched section is employed for all in each embodiment, and furthermore it is needless to say that a layer 17 made from poly-monochrolo-para-xylylene may be employed for the configuration in place of this configuration described above.

Fig.9 is a perspective view showing a stent as a whole according to Embodiment 5 using a rib different from that in each embodiment described above, and Fig. 10 is an enlarged side view thereof. A articulated rib 43 as a peripheral rib of the stent according to this embodiment also has a positioning function to prevent movement of the stent after retained, which is the same as that in each embodiment. The rib 43 is provided in an articulated shape with a portion in the peripheral direction thereof notched so that the cylindrical body can be squashed in the radial direction thereof on each side of edges of the external surface of the cylindrical body 42. It is assumed that an angle in the peripheral direction where the rib 43 is provided is set in a range from 180° to 300°, which is desirable for squashing the cylindrical body 42. Also this rib 43 is provided monolithically with the cylindrical body 42, and it is not necessarily to limit the shape to the form described above, and, for instance, the rib may be adhered to the cylindrical body with an adhesive after each of them has been formed discretely. Figure for configuration of a cylindrical body 42 other than the rib 43 is omitted herein, but any configuration in each embodiment described above may be employed.

In a case of the stent 41 having the rib 43 described above, when the stent is to be inserted into a section of sterosis of trachea, it is possible to insert it into an introducer for a rigid broncho-scope in a state where the stent has been squashed in the radical direction thereof, and for this reason the insertion thereof becomes easier than that with stents 1, 11, 21, and 31 in each embodiment described above.

Claims

1. A stent (1;11;21;31) for intracorporeal retention wherein said stent has a hollow cylindrical body (2) made from silicone rubber with both ends open, and an internal surface of this cylindrical body is processed in any of the following ways: (a) coating with silicone resin (4), (b) adhesion of a fluorine-based resin tube (14), or (c) chemical deposition of polyparaxylylene or a derivative thereof (17), and at the same an external surface (7) thereof is processed by (d) chemical deposition of polyparaxylylene (17) or a derivative thereof or (e) gradually rounding and tapering toward both ends with the ta-

pered sections (5) being softer than other portions thereof.

2. A stent (1;11;21;31) as claimed in claim 1, wherein a silicone resin layer (4) is formed so that it covers an internal surface of the cylindrical body, an external surface of each end section is recessed (5), a silicone rubber layer (6) softer than the cylindrical body is formed in each of the recessed sections, and an external surface of said silicone rubber layer is gradually rounded and tapered toward the end.

3. A stent (1;11;21;31) as claimed in claim 1, wherein a fluorine-based resin layer (14) is formed so that it covers an internal surface of the cylindrical body, an external surface of each end section is recessed (5), a silicone rubber layer softer than the cylindrical body is formed in the recessed section (6), and an external surface of said silicone rubber layer is gradually rounded and tapered towards the end.

4. A stent (1;11;21;31) as claimed in claim 1, wherein an external surface of each end section of the cylindrical body is recessed (5), a silicone rubber layer (6) softer than the cylindrical body is formed in said recessed section, an external surface of said silicone rubber layer is gradually rounded and tapered toward the end, and a layer made from polyparaxylylene or a derivative thereof (17) is formed so that it covers an internal and an external surface of the cylindrical body including said silicone rubber layer.

5. A stent (1;11;21;31) as claimed in claim 1, wherein a fluorine-based resin layer (14) is formed so that it covers an internal surface of the cylindrical body, an external surface of each end section is recessed (5), a silicone rubber layer softer than the cylindrical body is formed in said recessed section (6), an external surface of said silicone rubber layer is gradually rounded and tapered toward the end, and a layer made from polyparaxylylene or a derivative thereof (17) is formed so that it covers an external surface of the cylindrical body including said silicone rubber layer.

6. A stent (1;11;21;31) according to any one of the preceding claims provided with at least one peripheral rib (3) preferably at one or both ends.

7. A stent (1;11;21;31) according to claim 6 wherein said rib (3) is annular.

8. A stent (1;11;21;31) according to claim 6 or claim 7 wherein the or each rib is arcuate and provided with a recessed section so that the cylindrical body (2) can be compressed.

9. A stent (1;11;21;31) according to any one of claims 6 to 8 wherein said rib (3) is integral with the cylindrical body (2).

10. A stent (1;11;21;31) for intracorporeal retention comprising a hollow cylindrical silicone rubber body (2), said body being open at each end, wherein the internal surface of said body comprises a silicone-based material of increased lubricity (4), a fluorine-based resin (14) or polyparaxylylene or a derivative thereof (17) and an external surface (7) is coated with polyparaxylylene or a derivative thereof (37) and/or at least one end portion is smoothly rounded and gradually tapers towards the end thereof, said tapered end portion being softer than a central portion of the cylinder body (2).

FIG. 1

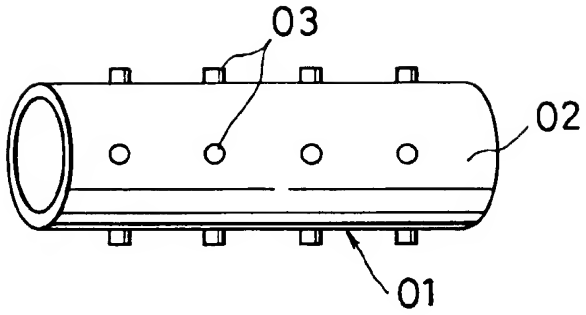


FIG. 2

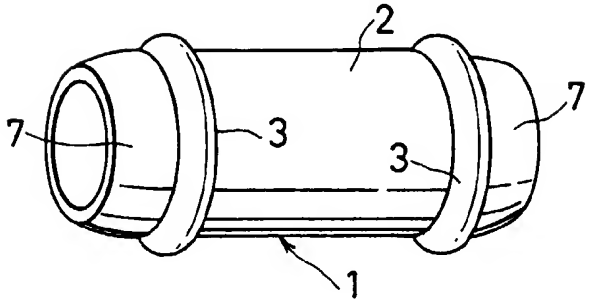


FIG. 3

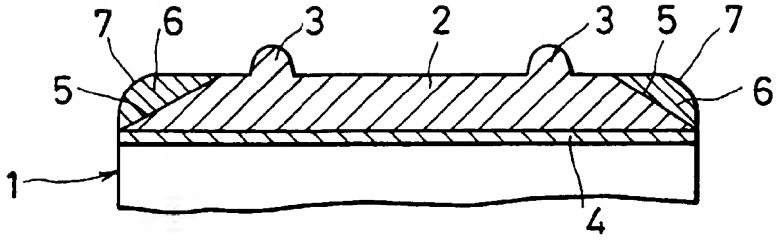


FIG. 4

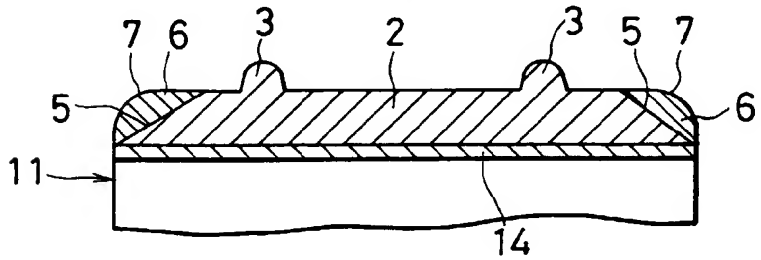


FIG. 5

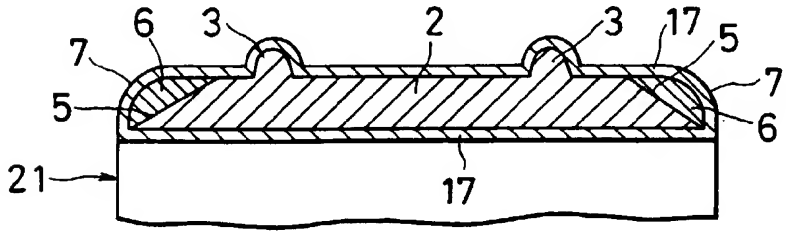


FIG. 6

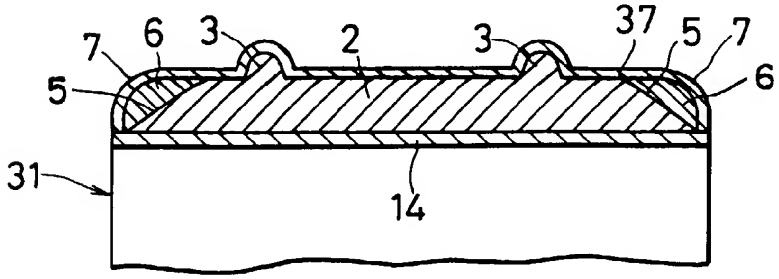


FIG.7A

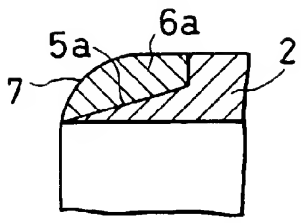


FIG.7B

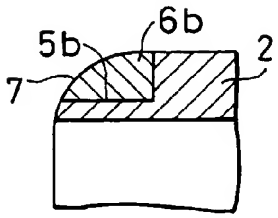


FIG.7C

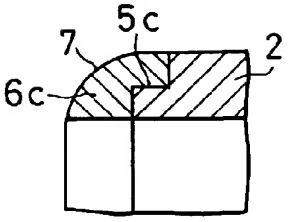


FIG.7D

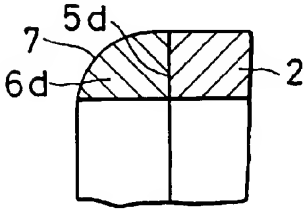


FIG.7E

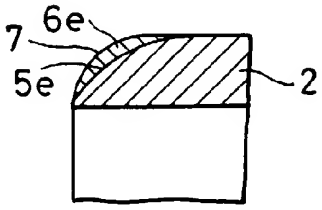


FIG.8

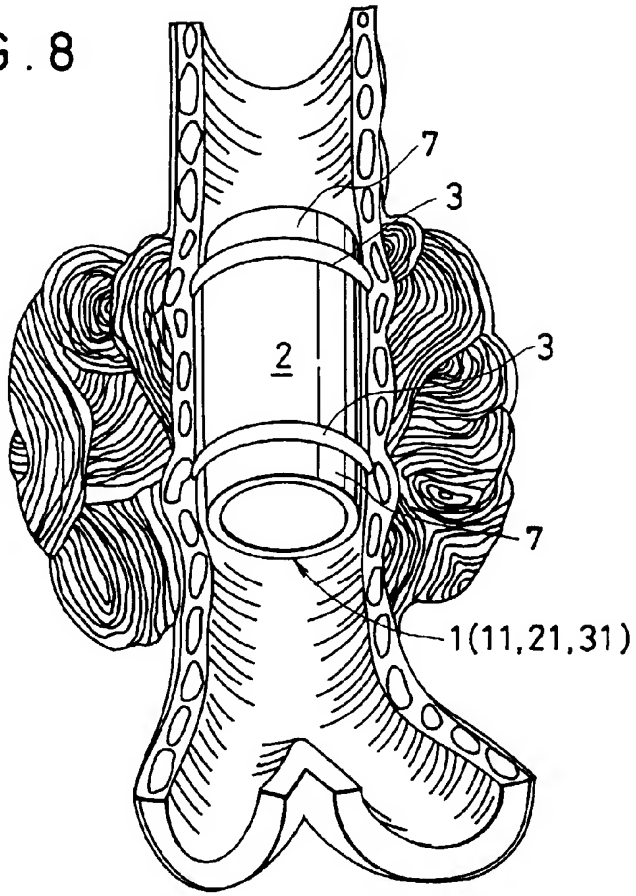


FIG. 9

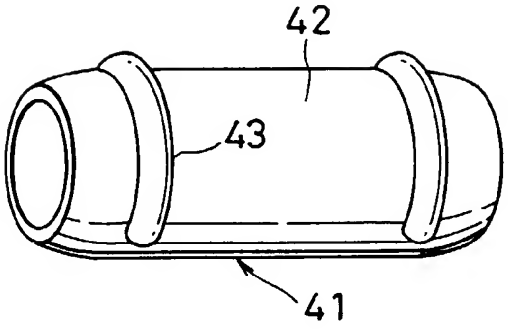
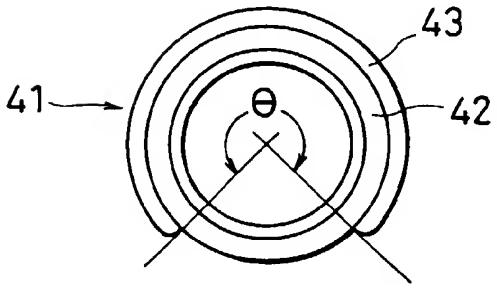


FIG. 10



European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 30 8805

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	SOVIET PATENT ABSTRACTS Section PQ, Week 9317 16 June 1993 Derwent Publications Ltd., London, GB; Class P32, AN 93-141865 XP002000386 & SU-A-1 732 964 (VITEB MED INST) , 15 May 1992 * abstract *	1,6,9,10	A61F2/04 A61F2/06
A	PATENT ABSTRACTS OF JAPAN vol. 095, no. 001, 28 February 1995 & JP-A-06 277239 (IZUMO RUBBER KOGOYO KK), 4 October 1994, * abstract *	1,10	
A	US-A-5 156 620 (PIGOTT) * column 4, line 4 - line 15; figures 1,2 *	1,10	
A	WO-A-80 01460 (AB TESI) * claims 1,2; figures 1A,B *	1,6-8,10	
A	WO-A-89 07916 (ARTEMIS ET AL.) * page 4, line 18 - line 26; claims 1,6-8; figures 1,4 *	1,10	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)
A61F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	11 April 1996	Kanal, P

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